

## **REMARKS**

### **Status of the Claims**

Claims 22, 25, 28-30, 32-39, 57, 58, and 60-95 are pending in this application, with claims 22, 28, 29, 32, 33, 38, 57, 60-62, 70, and 84 being independent. In the Office Action dated August 9, 2005, the Examiner rejected each claim under 35 U.S.C. § 103(a) in view of various combinations of U.S. Patent No. 4,832,047 to Sepetka et al. ("Sepetka"), U.S. Patent No. 4,984,581 to Stice ("Stice"), U.S. Patent No. 5,947,940 to Beisel ("Beisel"), U.S. Patent No. 4,932,419 to de Toledo ("de Toledo"), U.S. Patent No. 5,885,227 to Finlayson ("Finlayson"), U.S. Patent No. 5,997,517 to Whitbourne ("Whitbourne"), and U.S. Patent No. 5,174,302 to Palmer ("Palmer"). In addition, the Examiner rejected claim 38 under 35 U.S.C. § 102(e) in view of U.S. Patent No. 5,833,631 to Nguyen ("Nguyen").

With this amendment, Applicants have amended claims 33 and 70 to more clearly define the claimed invention. In addition, claims 22, 28, 29, 32, 38, 57, 60-62, and 84 have been amended to recite that the coil extends beyond the distal end of the core by a plurality of turns of the coil. Finally, minor amendments have been made to dependent claims 71, 73, and 76, and new dependent claims 90-95 have been added reciting that the polymeric material extends within spaces between adjacent turns of the coil. Support for these amendments is provided at least in drawing Fig. 2 and page 10, lines 5-15 of the specification. No new matter had been added.

### **Claim Rejections - 35 U.S.C. § 102**

In the Office Action, the Examiner rejected claim 38 as allegedly anticipated by Nguyen. Independent claim 38, recites, *inter alia*, a guide wire having an elongate core

including a proximal end and a distal end. The guide wire further includes a continuous coil that surrounds a portion of the core and extends beyond the distal end of the core by a plurality of turns of the coil. A polymeric tip contacts and extends from a distal portion of the coil, wherein the tip connects to the core by a polymeric material that extends between adjacent turns of the coil.

In rejecting claim 38, the Examiner points to column 4, lines 6-16 of Nguyen as disclosing the claimed polymeric material and asserts that “[w]hen shrunk, the polymeric material extends at least partially within spaces between adjacent turns of the coil.” (August 9, 2005 Office Action, at page 2.) Applicants assume the Examiner is pointing to the exterior polymeric tubing 112 disclosed in column 4, lines 6-16 of Nguyen as corresponding to the claimed polymeric material.

Applicants respectfully traverse this rejection for at least two reasons. First, Nguyen does not disclose or suggest, in any of its embodiments, at least the feature of a polymeric tip that connects to the core by a polymeric material that extends within spaces between adjacent turns of the coil, as recited in claim 38. In all three embodiments illustrated in FIGS. 1-3, the polymeric material (item 112 in FIGS. 1-2 and item 306 in FIG. 3) does not extend within spaces between adjacent turns of the coil, as claimed. In fact, FIGS. 1-3 of Nguyen clearly show that spaces between adjacent turns of the coil are not filled with polymeric material. Furthermore, nowhere does Nguyen disclose that the material 112 or 306 extends within spaces between adjacent turns of the coil.

Second, the cited passages in Nguyen relate to the embodiment of FIG. 1, where three separate and distinct coils (i.e. 106, 108, and 110) are provided along the length

of the device. Therefore, where the cited passages of Nguyen describe that “tubular covering (112) be of a material which can be shrunk down on and provide a measure of column strength to the fiber bundle,” it can only be assumed that covering 112 contacts bundle 104 in-between the distinct coil sections (106, 108, and 110) and not within spaces between adjacent turns of the coil as claimed. In the embodiment of FIG. 2, a single coil 204 is illustrated and expressly described as being coextensive with fiber bundle 202. (See Nguyen at column 4, lines 41-42.) In addition, the only disclosure relating to the arrangement of covering 112 in the second embodiment is FIG. 2, which expressly illustrates the spaces between adjacent turns of coil 204 as not being filled with polymeric material 112. Therefore, Nguyen provides no teaching or suggestion of a polymeric material extending within spaces between adjacent turns of the coil as claimed.

For at least the reasons presented above, Nguyen does not disclose or suggest the invention as recited in claim 38. Accordingly, Applicants respectfully request that the Section 102(e) rejection of independent claim 38 be withdrawn.

#### **Claim Rejections - 35 U.S.C. § 103**

In the Office Action, the Examiner rejected every independent claim under 35 U.S.C. § 103(a) as allegedly being obvious over combinations that included at least Sepetka in view of Stice, and in some cases a third reference. As amended, each of independent claims 22, 28, 29, 32, 38, 57, 60-62 and 84 recites, *inter alia*, a guide wire having an elongate core and a continuous coil that surrounds a portion of the core and extends beyond the distal end of the core by a plurality of turns of the coil. A polymeric tip extends from a distal portion of the coil, wherein the tip connects to the core by a

polymeric material. The claimed features of (1) a coil that extends beyond the distal end of the core by a plurality of turns of the coil and (2) the polymeric material provide the benefit of polymer that functions as a safety ribbon. This arrangement provides the advantages of a flexible guidewire tip, while eliminating the need for a metallic safety ribbon and guiding a metallic core into a safety ribbon. (See specification at page 10, lines 5-15.) In so far as the Examiner deems the rejections to apply to claims 22, 28, 29, 32, 38, 57, 60-62 and 84 as amended, Applicants respectfully traverse for at least the following reasons.

“To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation...to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure.” M.P.E.P. § 2143 (8<sup>th</sup> ed. Rev. May 2004), p. 2100-129, quoting *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The initial burden of establishing a *prima facie* case of obviousness is on the Examiner.

In the instant case, at least the third criteria is not met. Neither Sepetka nor Stice teach or suggest at least the claimed recitations of a coil that extends beyond the distal end of the core by a plurality of turns of the coil. For example, in Sepetka, the coil 30, at its distal end 36, does not extend even a full turn beyond the core 14 and definitely not by a plurality of turns as claimed. It would not have been obvious to extend the coil 30

of Sepetka a couple of turns for at least the reason that such a modification would require additional solder at joint 40, thereby rendering the tip less flexible.

Accordingly, for at least the reasons presented above, the proposed combination does not teach or suggest all the limitations of the claimed invention and therefore, the required burden is not met. Accordingly, Applicants respectfully request that the rejection of claims 22, 28, 29, 32, 38, 57, 60-62 and 84 as being unpatentable over Sepetka in view of Stice be withdrawn.

In addition, Applicants request that the rejections of dependent claims 25, 30, 34-37, 39, 58, 63-69, and 85-89 also be withdrawn because these dependent claims include additional patentable features as well as the limitations of their respective independent claims. None of the secondary references of Beisel, de Toledo, Finlayson, Whitbourne, or Palmer compensate for the deficiencies in the combination of Sepetka in view of Stice discussed above. Accordingly, Applicants respectfully request that the rejection of claims 22, 25, 28-30, 32, 34-39, 57, 58, 60-69, and 84-89 under Section 103(a) be withdrawn.

Independent claim 33 includes the recitation of a coil having a pitch that varies at least once therealong and independent claim 70 includes the recitation that a second coil portion has a greater pitch than a first coil portion. The Examiner rejected claims 33 and 70 under Section 103(a) setting forth that in Sepetka “[t]he coil includes a pitch that varies at least once along the core (Figure 4).” (August 9, 2005 Office Action, at page 3.) Applicants respectfully disagree with this statement.

Figure 4 of Sepetka merely discloses that coil 60 has a gradual reduction in diameter as it progresses proximally. (See e.g. Sepetka at column 6, line 34-50.) The

pitch (i.e. the distance between one point along a turn of the coil and the corresponding point along the next turn of the coil), however, appears to remain constant in Figure 4. In fact, the only portion of Sepetka where the word “pitch” appears does not suggest that there is any change. As set forth in column 6, line 65 - column 7, line 1, the disclosed second subsystem of Sepetka is configured for movement at a translational speed determined by “**the desired helical pitch** of the coil.” Therefore, the above cited passages of Sepetka do not disclose or suggest a variation in pitch.

Accordingly, for at least the reasons presented above, the proposed combination does not teach or suggest all the limitations of the claims 33 and 70 and therefore, the required burden is not met. Accordingly, Applicants respectfully request that the rejection of claims 33 and 70 as being unpatentable over Sepetka in view of Stice be withdrawn. In addition, Applicants request that the rejections of dependent claims 71-83 also be withdrawn because these dependent claims include additional patentable features as well as the limitations of their respective independent claims.

#### **NEW CLAIMS 90-95**

By this Amendment, Applicants have added new claims 90-95. None of the cited prior art, alone or in combination, teaches or suggests the recitations of claims 90-95. Applicants request examination and favorable consideration of the newly submitted claims.

#### **CONCLUSION**

In view of the foregoing remarks, this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application.

Applicants therefore request Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

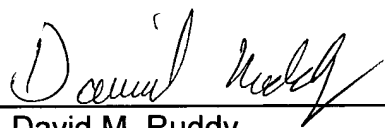
In discussing the specification, claims, and drawings in this Amendment, it is to be understood that Applicants are in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification and/or shown in the drawings. Rather, Applicants are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account no. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: November 14, 2005

By:   
David M. Ruddy  
Reg. No. 53,945